

Application No.: 09/826,267

6

Docket No.: 297912003900

REMARKS

At the outset, Applicants note with appreciation the Examiner's indication of allowable subject matter in claims 19 and 21. Claims 1-16 and 23-29 have been withdrawn from further consideration by the Examiner as being drawn to a non-elected invention. Claims 1-16 and 23-29 are canceled by this amendment. Applicant expressly reserves the right to pursue these canceled claims in continuation and/or divisional applications. Claim 17 has been amended. Claims 30-37 have been added, support for which can be found in claims 17 and 20-22 as originally filed, in the specification on p. 2, lines 10-17, in the specification on pp. 6-7, and in FIGS. 3 and 7. No new matter has been added.

Prior Art Rejections**A. Myers et al. in view of Goldmann et al.**

Claims 17, 18 and 22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over USPN 5,810,870 to Myers et al. (Myers) in view of USPN 6,053,938 to Goldmann et al. (Goldmann). The Examiner has conceded that while Myers teach the method of forming an intraluminal stent graft and collapsing to a collapsed diameter so that it may be inserted into a delivery sheath, the required step in the rejected claims of altering the surface of the biocompatible layer is missing therefrom. However, the Examiner has taken the position that it would have been obvious to one of skill in the art, and one of skill in the art would have been motivated, to alter the surface of the coated stent in the process of Myers using either of the pleating techniques taught by Goldmann (*i.e.*, pleating the prosthesis while supported on a conical template and shrinking the prosthesis so that it conforms to the shape of a template in the form of a round bar having on its surface a slight corrugation or transverse ribs). Applicants respectfully traverse this rejection.

Applicants respectfully submit that a *prima facie* case of obviousness has not been established for at least the following reasons: 1) neither Myers nor Goldmann teach the step of altering a surface of a biocompatible layer; 2) Myers and Goldmann are non-analogous art and therefore the combination is improper; and 3) there is no suggestion or motivation to combine Myers with Goldmann.

oc-270878

Application No.: 09/826,267

7

Docket No.: 297912003900

- 1) Neither Myers nor Goldmann teach the step of altering a surface of a biocompatible layer

The Examiner has conceded that Myers does not teach the required step of altering a surface of a biocompatible layer. However, the Examiner states that this missing step is provided by Goldmann with reference to the disclosure of forming a pleating in a knitted or woven conical prosthesis through the use of heating processes. Goldmann teaches that pleating can be accomplished either before or after producing the conical form as follows:

"If a pleating is desired, then the latter is preferably formed beforehand, when the prosthesis blank is located on the conical flat bar. For this purpose on either side of the conical flat bar transversely directed hot embossings can be made at intervals from one another in the tube wall and they form the subsequent depressions of the pleating. The transversely directed hot embossings need not cover the entire circumference of the prosthesis tube, even though this is normally the case. A partial prior formation of the depressions is adequate. According to a further development of the process according to the invention, despite the conical structure of the prosthesis drawn onto the conical flat bar, the size of the embossed strips is to be kept constant over the entire length. The expression end of the flat bar does not mean that the latter ends here. In this vicinity of the conical flat bar it is also possible to provide a marking or width step and a reduction of the width is preferred, because this also favours the application of clamping devices, which can be used for fixing the length of the prosthesis on the flat bar." (col. 3, lines 40-58)

"According to another embodiment of the process according to the invention, more particularly woven prosthesis blanks can be used with a calibre or gauge, whose inner circumference corresponds to the circumference of the conical template at the larger end. The prosthesis blanks drawn onto the conical template can then be shrunk onto the conical template utilizing the fibre shrinkage of shrinkable fibres and accompanied by a calibre reduction. In this embodiment the conical template is preferably constituted by a conical round bar. If here again a pleating is desired, then it is preferably formed beforehand at the same time as shrinking the calibre. For this

oc-270878

Application No.: 09/826,267

8

Docket No.: 297912003900

prior formation it is appropriate to use conical templates in the form of round bars with transversely directed corrugations or ribs, whose spacings correspond to those of the pleating." (col. 3, line 59 to col. 4, line 6).

"The formation of a pleating after producing the conical form by shrinkage on a conical flat bar using conventional processes by folding in prostheses is also possible." (col. 4, lines 7-9).

Applicants contend that formation of pleating through the use of hot embossings, conical templates with round bars having transversely directed corrugations or via conventional folding processes is not the same as the step of altering a surface of a biocompatible layer as claimed. Further, nowhere in the teaching of Goldmann can such a step be found. Therefore, in view of the above, Applicants submit that the step of "altering a surface of a biocompatible layer" as claimed is not taught, disclosed or suggested by Goldmann and respectfully request reconsideration by the Examiner.

2) Myers and Goldmann are Non-Analogous Art

In order to be analogous art, the references must be from the same field of endeavor or, if not, then be reasonably pertinent to the particular problem with which the invention is concerned. (See MPEP 2141.01(a)). As the Examiner has noted, Myers is directed to an intraluminal stent graft that is collapsable for insertion into a delivery assembly. The term "intraluminal" is defined as within a blood vessel. Goldmann, on the other hand, is directed to an artificial vessel prostheses for replacing blood vessels and other hollow organs. Consequently, the prosthesis of Goldmann is not analogous to the intraluminal stent graft of Myers in the context of the pending claims. Moreover, in view of the above, it is apparent that Goldmann is not reasonably pertinent to the particular problem for which the invention is concerned (*i.e.*, preparing an implantable prosthesis for intraluminal delivery which may include facilitating the loading thereof into a delivery apparatus). As such, Applicants submit that the art of Myers and Goldmann are non-analogous and respectfully request reconsideration by the Examiner.

oc-270878

Application No.: 09/826,267

9

Docket No.: 297912003900

3) No Suggestion or Motivation to Combine Myers and Goldmann

"There are three possible sources for a motivation to combine references; the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

Here, the nature of the problem to be solved by the present invention is explained in the specification:

"The present invention relates to devices and methods to facilitate the loading of a prosthesis into a delivery apparatus. More particularly, the present invention is related to devices and methods for forming alterations in the prosthesis to make collapsing of the prosthesis easier by reducing frictional forces acting thereon during the process of loading the prosthesis into a delivery apparatus. Advantageously, creation of alterations in the prosthesis enables a more compact collapse, leading to a smaller insertion profile. This is beneficial to both the physician and patient as complications inherent with the insertion of prostheses are largely reduced." (p. 2, lines 10-17).

With reference to the *In re Rouffet* sources for motivation, the nature of the problem to be solved is nowhere mentioned in Goldmann as Goldmann is directed to a replacement prosthesis rather than a prosthesis for intraluminal delivery. Further, as discussed above, neither Myers nor Goldmann teach the step of altering a surface of a biocompatible layer. Moreover, Applicants submit that one of ordinary skill in the art would not look to a patent directed to a bulky textile artificial vessel prosthesis for replacing blood vessels and other hollow organs to modify a low-profile intraluminal stent graft.

Also, it is important to note that if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Myers is directed to an intraluminal stent graft having a covering of porous expanded

oc-270878

Application No.: 09/826,267

10

Docket No.: 297912003900

polytetrafluoroethylene which is less than 0.10 mm thick. Myers teaches that a thin-walled graft is desirable for affixing to an adjustable stent so that invasive surgery can be avoided. (col. 1, lines 48-57). It is undeniable that the pleated prosthesis of Goldmann would render the Myers intraluminal stent graft unsatisfactory for its intended purpose due to the large profile that would be created as a result of the combination. Therefore, in view of the above, Applicants assert that there is no motivation or suggestion to combine these references and respectfully request reconsideration by the Examiner.

In view of the above, Applicants submit that claims 17, 18 and 22 are not unpatentable under 35 U.S.C. §103(a) over a combination of Myers and Goldmann and therefore respectfully request withdrawal of this rejection.

B. Myers in view of Ketcham and Goldmann

Claims 17, and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Myers in view of USPN 4,427,616 to Ketcham when taken in view of Goldmann. The Examiner has conceded that while Myers teach the method of forming an intraluminal stent graft and collapsing to a collapsed diameter so that it may be inserted into a delivery sheath, the required step in the rejected claims of altering the surface of the biocompatible layer is missing therefrom. However, the Examiner has taken the position that it would have been obvious to one of skill in the art, and one of skill in the art would have been motivated, to alter the surface of the coated stent in the process of Myers using the convoluting technique taught by Ketcham, when taken in view of the teaching of Goldmann that it was known to alter the surface of a prosthesis. Applicants respectfully traverse this rejection.

In view of the comments above, Applicants submit that a *prima facie* case of obviousness has not been established for at least the following reasons: 1) neither Myers, Ketcham, nor Goldmann teach the step of altering a surface of a biocompatible layer; 2) Myers and Ketcham in view of Goldmann are non-analogous art and therefore the combination is improper; and 3) there is no suggestion or motivation to combine Myers with Ketcham in view of Goldmann.

oc-270878

Application No.: 09/826,267

11

Docket No.: 297912003900

First, as discussed above, neither Myers nor Goldmann teaches the step of altering a surface of a biocompatible layer. Ketcham does not supply this missing disclosure as, similar to Goldmann, the teaching thereof is with respect to formation of a convoluted configuration in TEFLON tubing, using shaped mandrels and heat inside an insulated oven. Such disclosure is not the same as altering a surface of a biocompatible layer, as explained above.

Second, the combination of Ketcham in view of Goldmann does not result in a teaching that is analogous to Myers. Initially, one of ordinary skill in the art would not look to Ketcham for modification ideas for Goldmann. Goldmann is directed to a conical textile vessel prosthesis produced by knitting or weaving a constant number of yarns or threads in cross-section over the entire length thereof (col. 2, lines 1-6). Ketcham is directed to an apparatus and method for convoluting TEFLON tubing, presumably so that the tubing may be used as parts for engines or as cable components, in which the convoluted configuration aids in the prevention of kinking. One of ordinary skill in the art would not look to a patent directed to a non-textile material in a completely different art area for modification of a product which specifically differentiates non-textile materials (see col. 1, lines 34-43). Moreover, even if Ketcham and Goldmann were combinable, the combination thereof would decidedly not be analogous to the intraluminal stent-graft of Myers, as set forth above.

Third, it is unmistakable that there is no motivation to combine these references, largely for the reasons set forth above, with the additional factor that Ketcham is directed to a completely different art area such that one can only conclude that any combination for purposes of a prior art rejection would necessarily be hindsight in nature.

Therefore, in view of the above, Applicants submit that claims 17 and 20 are not unpatentable under 35 U.S.C. §103(a) over a combination of Myers and Ketcham in view of Goldmann and therefore respectfully request withdrawal of this rejection.

Summary

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to

oc-270878

Application No.: 09/826,267

12

Docket No.: 297912003900

withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 297912003900. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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oc-270878